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§17–202.

(a) (1) The Secretary shall adopt regulations that set standards and requirements for medical laboratories.

(2) The regulations shall contain the standards and requirements that the Secretary considers necessary to assure the citizens of this State that medical laboratories provide safe and reliable services.

(b) To assure compliance with the standards and requirements adopted in regulations pursuant to this subtitle, the Secretary shall:

(1) Conduct an inspection of each medical laboratory for which a license to operate is sought; and

(2) Conduct an inspection periodically of each medical laboratory for which a license has been issued.

(c) (1) In addition to the regulations adopted under subsection (a) of this section, the Secretary shall adopt regulations establishing specific standards for medical laboratories engaged in cytology, including regulations that:

(i) Limit the number of slides an individual may examine;

(ii) Require that the examination of cytology slides be performed in a medical laboratory that has a license issued by the Secretary;

(iii) Prohibit payment to cytotechnologists for the examination of cytology specimens or slides on a piecework basis;

(iv) Require cytology laboratories to review no less than 10 percent of all negative gynecological slides;

(v) Require that the cytology review be performed by an individual who qualifies as a supervisory cytotechnologist or a pathologist;

(vi) Require the individual who directs the laboratory to establish and administer an ongoing quality assurance program using standards acceptable to the Secretary;

(vii) Require cytology laboratories to reject unsatisfactorily prepared specimens, make appropriate comments regarding the quality of the specimen, and maintain records on unsatisfactorily prepared specimens for 5 years subject to review by the Department;

(viii) Require cytology laboratories to maintain and store for 5 years from the date of examination any slide that was examined;

(ix) Require all cytology reports to be retained for at least 10 years;

(x) Prohibit any person from sending cytology specimens to a laboratory, including out–of–state laboratories, not licensed by the Department;

(xi) Require all individuals who examine gynecological slides acquired from persons in this State to demonstrate satisfactory performance in an approved cytology proficiency testing program; and

(xii) Establish any additional standards the Secretary considers necessary to assure that medical laboratories engaged in cytology provide safe and reliable services.

(2) The requirements of paragraph (1) of this subsection are in addition to any other relevant provision of this subtitle or relevant regulation adopted in accordance with any other provision of this subtitle governing medical laboratories.

(d) (1) To assure compliance with standards adopted under subsection (c) of this section, the Secretary shall adopt regulations to establish and conduct a cytology proficiency testing program for all cytology personnel that examine gynecological cytology specimens.

(2) All cytology proficiency tests under the State cytology proficiency testing program shall be conducted by an employee of the Maryland Department of Health who shall:

(i) Hand carry all testing materials to the testing site; and

(ii) Directly supervise the on–site proficiency testing.

(3) The Secretary shall adopt regulations for the cytology proficiency testing program that:

(i) Define satisfactory cytology proficiency testing performance; and

(ii) Set standards and requirements that a cytology proficiency testing program must meet before it can be designated an approved program.

(4) The Secretary may accept the testing results of an approved cytology proficiency testing program as meeting the cytology proficiency testing requirement of this subtitle.

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